

In re Application of: Lola WEISS et al  
Serial No.: 10/589,623  
Filed: August 16, 2006  
Office Action Mailing Date: July 6, 2010

Examiner: Jennifer M. KIM  
Group Art Unit: 1628  
Attorney Docket: 32361  
Confirmation No.: 3826

### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-25 are in this Application. Claims 19-23 have been withdrawn from consideration. Claims 1-18 and 24-25 have been rejected under 35 U.S.C. § 112. Claims 1-6 and 8-18 have been rejected under 35 U.S.C. § 102. Claims 7, 11 and 24-25 have been rejected under 35 U.S.C. § 103. Claims 6-7, 11-18 and 25 have been canceled herewith. Claims 1, 2 and 4 have been amended herewith. New claim 26 has been added herewith.

### **Amendments To The Claims**

#### **35 U.S.C. § 112 Rejections**

The Examiner rejected claims 1, 4-11, 14-18, 24 and 25 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner states that the instant specification does not provide ample species support for the phrase "a cannabidiol". Examiner's rejection is respectfully traversed. Claim 1 has been amended herewith to remove the "a" and to further clarify that the cannabidiol used is CBD. CBD is an art accepted term (see for example R&D Profile 2003 and Hampson et al. WO99/53917, each of which cited by the Examiner). Support for the amendment can be found in Page 4 line 15 - "*Cannabidiol (CBD) is present in most Cannabis preparations (hashish, marijuana, ganja).*"

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Withdrawal of the rejection is respectfully requested.

The Examiner further rejected claims 1-18 under 35 U.S.C., first paragraph, because the specification is allegedly not enabling for prevention of diabetes.

Examiner's rejection is respectfully traversed. Claims 8-18 have been cancelled herewith.

The Examiner is mistaken in asserting that the specification provides minimal guidelines to prevention of diabetes with NO working examples. In fact, Example 1 of the instant specification specifically teaches prevention of diabetes (Tables 1 and 2) and insulinitis (Table 3) using CBD. Example 2, on the other hand, teaches treatment of progressed diabetes. Hence, in sharp contrast to Examiner's statements, the instant specification fully enable prevention of diabetes in a clinically relevant animal model. Withdrawal of the rejection is respectfully requested.

35 U.S.C. § 102 Rejections

The Examiner rejected claims 1-6 and 8-18 under 35 U.S.C. § 102 as being anticipated by R&D Profile record (2003). Specifically, the Examiner states that R&D profile teaches a combination of THC and CBD for the treatment of peripheral neuropathy secondary to diabetes mellitus. Examiner's rejection is respectfully traversed. Claim 1 has been amended to include the limitation of non-rejected claim 7 i.e., Type II diabetes.

Notwithstanding, Claim 26 has been added to recite that the CBD is comprised in a composition devoid of psychotropic activity. The art of R&D profile clearly teaches psychotropic compounds, by virtue of comprising THC. Support for "lack of psychotropic activity" can be found on page 8 line 32.

For the above amendment and arguments, withdrawal of the rejection is requested.

The Examiner rejected claims 1-6 and 8-18 under 35 U.S.C. § 102 as being anticipated by Hampson et al. (WO 99/53917). Specifically, the Examiner states that

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Hampson et al. teach CBD for the treatment of autoimmune diseases such as diabetes and further teaches the claimed routes for administration. Examiner's rejection is respectfully traversed. Claim 1 has been amended to include the limitation of non-rejected claim 7. Claims 8-18 have been cancelled herewith.

For the above amendment and arguments, withdrawal of the rejection is requested.

35 U.S.C. § 103 Rejections

The Examiner has rejected claims 7, 11 and 24-25 under 35 U.S.C 103, as being unpatentable over Hampson et al. (supra) in view of Hill (WO 02/13814).

Specifically, while acknowledging that Hampson et al. do not teach treatment of type II diabetes, the Examiner states that Hill teaches that type 1, 2 diabetes and insulinitis are dysfunctions of islet and that particularly insulinitis and type 1 are autoimmune diseases. The Examiner concludes that it would have been obvious to the skilled artisan to employ the CBD taught by Hampson et al. for the treatment of the claimed indications since Hampson et al. teach that CBD is useful for the treatment of autoimmune disorders and because Hill teaches that type I diabetes and insulinitis are autoimmune disorders and type II is similarly treated with conditions of type I and insulinitis.

Examiner's rejection is respectfully traversed.

For clarity, Applicants are describing the teachings of Hampson et al. and Hill individually but are traversing the rejection with respect to the combination of these references, *infra*. That is, the Applicants are not attacking the references individually, rather addressing the combinations of references as set forth in the instant Office Action.

In sharp contrast to Examiner's assertion, Hill does not teach that type I and type II diabetes are generally treated using the same medications. Hill teaches that administration of methionine containing amino acids can be used for inhibiting islet

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dysfunction. Islet dysfunction may be considered as a common feature of type I diabetes and advanced type II diabetes. Therefore, the art of Hill is unique in its ability to treat these very distinct diseases i.e., type I and type II diabetes, using medications which inhibit islet dysfunction. However, in sharp contrast, the art of Hampson et al. makes use of CBD for treating autoimmune diseases i.e., type I and not type II diabetes. Hampson et al. only suggests treatment of diabetes in the context of autoimmune diseases. See page 11 lines 17-18:

hypoxia or anoxia), spinal cord trauma, Down's syndrome, Crohn's disease, autoimmune diseases (e.g. rheumatoid arthritis or diabetes), cataract formation, uveitis, emphysema, gastric ulcers,

In this case, the drugs provided by Hampson target autoimmune diseases and as such can't be used for the treatment of type II diabetes, which does not share an autoimmune background. Indeed for this reason, immunotherapeutic agents (e.g., anti CD3, anti CD4, cyclosporine, azathioprine and prednisone) are used for the treatment of type I diabetes but not for treating type 2 diabetes.

In view of the above arguments it is respectfully requested to withdraw the rejection.

### **Conclusion**

In view of the above amendments and remarks it is respectfully submitted that claims 1-5, 8-10 and 26 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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